1. NAME OF THE VETERINARY MEDICINAL PRODUCT

APIGUARD MULTIDOSE 0.25 g/g bee-hive gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance

Thymol……..0.25g

Excipients:

Qualitative composition of excipients and other constituents
Carbomer
Triethanolamine
Water, purified

Slightly opalescent, colourless to pink granular gel.

3. CLINICAL INFORMATION

3.1 Target species

Honeybees (*Apis mellifera*).

3.2 Indications for use for each target species

Treatment of varroosis due to *Varroa destructor.*

3.3 Contraindications

None.

3.4 Special warnings

Care should be taken to ensure that the authorised dosage schedule is adhered to as improper dosing could deleteriously affect the colony.
The veterinary medicinal product should be used as part of an integrated varroa control program.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Do not treat during honey flow to avoid potential taste tainting.
The treatment can be performed immediately after the removal of the supers.
Do not use the veterinary medicinal product when the maximum daily temperature expected during the treatment is lower than 15°C or when the colony activity is very low or when temperature is above 40°C.
Combine weak colonies before treatment.
All colonies of an apiary should be treated simultaneously.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Personal protective equipment consisting of impermeable gloves should be worn when handling the veterinary medicinal product.

Because of possible contact dermatitis and irritation of the skin and eyes, direct skin and eye contact should be avoided.

When handling the veterinary medicinal product, wear impermeable gloves as well as the usual protection equipment.
After application, wash hands and the material being in contact with the gel with soap and water.
In case of skin contact, wash thoroughly the affected area with soap and water.
In case of eye contact, wash the eyes thoroughly with copious amounts of clean running water and seek medical advice.
Do not inhale.

People with known hypersensitivity to Thymol should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Honeybees (*Apis mellifera*).

Rare (1 to 10 animals / 10,000 animals treated, including isolated reports):	Agitation[1] Bee brood mortality[2], brood removal[3]

[1]Slight, during the treatment
[2]At high temperature a slight reduction in young brood can occur during the treatment period; this is transient and has no effect on the development of the colony
[3]Localised. Normal bee behaviour involves removing or cleaning the gel from the container above the brood frames with no effect on the colony; however, especially with more hygienic strains, some bees may occasionally remove uncapped bee brood from the vicinity of the veterinary medicinal product also. If this is observed, remove the veterinary medicinal product from the colony.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

In-hive use

Treatment in the hive: two applications of 50 g of gel (12.5 g thymol/dose) per colony at a 2-week interval.

Maximum of two treatments per year

Method of administration

Open the hive. Place the dosing card (supplied) in the middle above the brood frames. The veterinary medicinal product should be mixed well before use with a hive tool or similar for 10 seconds. Using the dosing syringe (supplied), transfer the first dose of 50 g of gel from the container to the dosing card as follows:

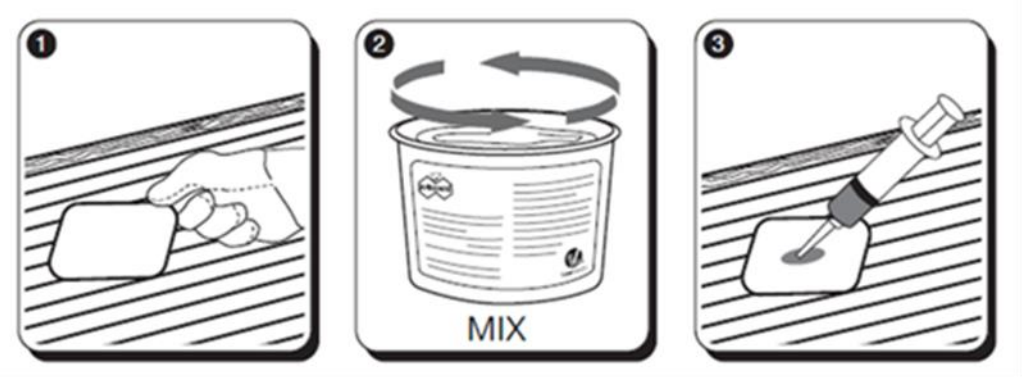
Remove the dosing syringe from its sealed package. Push the syringe nozzle all the way into the gel, making sure that no air enters the syringe. Slowly pull back on the plunger to aspirate 52 ml (equivalent to 50 g) of gel. Pull the syringe out of the gel. Gently push the plunger to release the gel from the syringe progressively to the entire surface of the dosing card. .

Make sure that there is a free space of at least 0.5 cm between the top of the gel and the lid of the hive. Close the hive.

After completion of administration of the treatment to beehives, wash the syringe in warm water. Pull out the plunger completely and wash the apparatus thoroughly to remove traces of gel. Allow to dry and store in a sealed container until next use.

After 2 weeks replace the first dosing card with a new one and apply the second dose of 52ml (equivalent to 50g) gel following the same procedure.

Leave the veterinary medicinal product in the colony for a further 2 weeks until it totally disappears from the dosing card. Remove the veterinary medicinal product when installing the supers on the colony. Please see the pictograms below:



The efficacy of Apiguard Multidose is maximised if the veterinary medicinal product is used in late summer after the honey harvest (when the amount of bee brood present is diminishing). However, in the case of severe infestations, this veterinary medicinal product can also be used during springtime, when temperatures are above 15ºC.

Efficacy may vary between colonies due to the nature of the application. Therefore, the veterinary medicinal product should be used as one treatment among others within an Integrated Varroa control program, and mite fall regularly monitored. If further significant mite fall is observed during the following Winter or Spring, it is recommended to use an additional secondary Winter or Spring treatment for varroa.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The use of a dose higher than the recommended (50 g gel per application corresponding to 12.5 g of thymol) could cause disturbances in the behaviour of the colony (agitation, absconding, or increased mortality). In case of overdose, remove the excess veterinary medicinal product from the colony.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

3.12 Withdrawal periods

Honey: zero days.
Do not use during honey flow.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP53AX22

4.2 Pharmacodynamics

Thymol has acaricidal action. However, its exact mode of action is not fully understood. It acts directly on the mites through inhalation and contact.
Protein denaturisation is one of the probable modes of action in mites.

4.3 Pharmacokinetics

It is thought that 2/3 of the action is elicited by inhalation and 1/3 by direct contact through honeybees. However, the relative proportion of each route may vary with temperature and honeybee activity.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 3 years (and before the expiry date).

5.3 Special precautions for storage

Do not store above 30°C.
Do not freeze.
Keep the container tightly closed.
Protect from direct sunlight.
Do not store the veterinary medicinal product near pesticides or other chemical substances which could contaminate the veterinary medicinal product.
Store away from foodstuffs.
The remaining dosing cards should be kept in a dry and clean place.
Always load the cards with gel in a well ventilated area.
Keep the remaining dosing cards in the outer cardboard box

5.4 Nature and composition of immediate packaging

Cardboard box containing 2 containers of 3000g, 2 syringes and 4 sealed packs of 30 dosing cards.

Single 3000g container, 1 syringe and 2 sealed packs of 30 dosing cards
3000g Polypropylene container with a polypropylene lid.
Polypropylene Syringe
Polyethylene/Paper/Polyethylene dosing card

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as thymol may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vita Bee Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22752/001/002

8. DATE OF FIRST AUTHORISATION

13/05/2022

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

04/06/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription. (ES, FR, IE, IT, SE)
Veterinary medicinal product subject to prescription. [PL]

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).